



October 2015

SETTING THE TABLE

Current Issues in Food Transport, Storage and Security from Benesch's Transportation & Logistics Practice Group

Food Safety Does Not Exist In A Vacuum, and Neither Do the FSMA's Rules: What the New Rules on Preventive Controls for Human and Animal Food Mean for Transportation



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On September 17, 2015 the FDA published the first two of its seven rules in conjunction with the Food Safety Modernization Act's (the "FSMA") regulatory scheme. The rules, which focus on Current

Good Manufacturing Practices ("CGMPs") for human and animal food,¹ mark the first final (and soon, enforceable) rules under FSMA (the "Final Rules").

Although the FSMA is intended to function as a single broad regulatory framework, the FDA has, for ease of implementation, compartmentalized this framework into seven purportedly distinct areas of responsibility, to be governed by federal regulations established through the agency's rulemaking process. Without question, the rule most closely watched by those in the transportation industry is the rule for the Sanitary Transportation of Human and Animal Food (the "Transportation Rule"), anticipated to be finalized by March 31, 2016.

While food transporters will continue to await the Transportation Rule, it is critical for those in transportation to be aware that the recently published Final Rules require cooperation from them as well.

What is in the Final Rules?

The Final Rules provide guidelines geared towards those in the manufacturing and processing of food, and requires all such covered entities to implement CGMPs. The Final Rules further require that covered entities implement comprehensive food safety plans which, among other things, contain a written "supply-chain program" for materials containing hazards requiring a "supply-chain-applied control," meaning a control necessary to be performed to eliminate a hazard sometime prior to the covered entity's receipt of the affected product. Deadlines for compliance with the Final Rules begin for some businesses as early as September 2016.

What Does this Mean for Transportation?

Food safety does not exist in a vacuum. As numerous comment letters to the FDA have pointed out, there is necessary interplay between food processors and those transporting the food. The FDA acknowledged these comments in its final rule, providing "[s]ome comments ask us to clarify how the requirements of this rule apply to transportation practices and assert that a facility receiving product should not be responsible for hazards in foods that are not being transported under its custody." 80 FR at 56032. Some commentators have gone further, requesting that the FDA

mandate "all entities across the supply chain to identify food transportation as a critical control point under the facility's hazard analysis." *Id.*

The FDA punted on these concerns, stating that it would "address comments regarding the responsibilities of shippers and receivers in the final sanitary transportation rule," but further stated that "we expect a facility that identifies temperature control, including during transportation, as a preventive control (whether or not as a [critical control point]), to communicate the need for appropriate temperature control to the person transporting the food." 80 FR 56032.

Thus, although the FDA declined to transform its latest rule into a de-facto sanitary transportation rule, those involved in food transportation are similarly not granted a pass to ignore this rule's requirements and await the Transportation Rule, either.

The Bottom Line

Although the new rule does not target transportation specifically, it does require covered entities involved in the processing of food to scrutinize their supply chain, and will require carriers and others involved in transportation to be partners in the required food safety plans. As food manufacturers begin

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to implement their food safety plans, so too should food transporters.

As initial steps, food transporters should ensure they are familiar with the food safety plans of the food products they are carrying, and must develop, refine, and implement their plans to maintain temperature control oversight of temperature sensitive food in their possession. Taking these steps now, instead of awaiting further regulation, will be required for manufacturer compliance with the Final Rules. Moreover, in light of the imminent finalization of the Transportation Rule, delay in taking these steps will only serve to delay the inevitable.

¹See Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Final Rule, 80 FR 55908, and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Final Rule; 80 FR 56170.

For more information

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